Remarks

Reconsideration of this Application is respectfully requested.

In response to the Notice to Comply, Applicants note that a paper copy of the substitute Sequence Listing, a computer readable form of the substitute Sequence Listing, an amendment directing entry of the Sequence Listing into the specification, and a statement that the paper copy of the Sequence Listing and the computer readable copy of the Sequence Listing are the same were submitted with the Amendment and Reply Under § 1.111 filed on August 22, 2008. Photocopies of the aforementioned documents (exclusive of the Sequence Listing diskette) and of the date-stamped postcard acknowledging receipt of the same by the USPTO are submitted herewith. In view of the foregoing, Applicants submit that the application is in full compliance with the requirements of 37 C.F.R. §§ 1.821-1.825.

In a telephone conversation between the undersigned and Examiner Baum on January 7, 2009, Applicants indicated to Examiner Baum that the DNA sequence recited in claims 10, 17, 18 and 21 is found in the substitute sequence listing that was filed on August 22, 2008. Examiner Baum agreed that Applicants did not need to file another substitute sequence listing but requested that Applicants amend claims 10, 17, 18 and 21 to replace the recited DNA sequence with the sequence identifier, SEQ ID NO:23.

Thus, upon entry of the foregoing amendment, claims 10, 14, 15, 17, 18, 21 and 41-48 are pending in the application, with claims 10, 17, 18 and 21 being the independent claims. Claims 10, 17, 18 and 21 are sought to be amended. Support for the amendment to the claims may be found in the specification at page 4, lines 5-7 and page 9, lines 15-17 and in the substitute sequence listing filed August 22, 2008. These

Amdt. dated January 23, 2009 - 7 - Reply to Notice to Comply dated December 23, 2008

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changes are believed to introduce no new matter, and their entry is respectfully requested.

Prompt and favorable entry and consideration of this Supplemental Amendment are respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

anna a. Camel

Shannon A. Carroll, Ph.D. Attorney for Applicants Registration No. 58,240

Date: January 23, 2009

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600 925499_1.DOC

SEQUENCE LISTING

| <110> | Chan, Lia Raquel Gonzalez, Daniel H. Dezar, Carlos A. Gago, Gabriela Marisa Dunan, Claudio Marcelo | |
|---------------------------|---|-----|
| <120> | Transcription Factor Gene Induced by Water Deficit Conditions Abscisic Acid from Helianthus Annuus, Promoter and Transgenic | |
| <130> | 2510.0040000/JAG/SAC | |
| <140> <141> | 10/520,333 2003-05-02 | |
| <150> <151> | PCT/US2003/013770 2003-05-02 | |
| <160> | 30 | |
| <170> | PatentIn version 3.1 | |
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| | caac aagtacccac aacagaaaca accaccagga agaaccgaaa cqaqqqqqqq | 120 |
| | ttta ccgacaaaca aataagtttc ctagagtaca tgtttgagac acagtcgaga | 180 |
| | ttaa ggatgaaaca ccagttggca cataaactcg ggcttcatcc tcgtcaagtg | 240 |
| | tggt tccagaacaa acgcgcgcga tcaaagtcga ggcagattga gcaagagtat | 300 |
| | ctaa agcataacta cgagacqctt gcqtctaaat ccqaqtctct aaaqaaaqaq | 360 |
| | gece tacteaatea ggtatggttg caaacttaca atgttgcatt caactattta | 420 |
| | tttg aatttttgtg acaataaaga ttgacaaatg ttgtttgata attgattaac | 480 |
| | aggt gctgagaaat gtagcagaaa agcatcaaga gaaaactagt agtagtggca | 540 |
| | aaga atcggatgat cggtttacga actctccgga cgttatgttt ggtcaagaaa | 600 |
| | ttcc gttttgcgac ggttttgcgt actttgaaga aggaaacagt ttgttggaga | 660 |
| | aaca actgccagac cctcaaaagt ggtgggagtt ctaaagagta aagaaggatg | 720 |
| | tagt agagtaaaaa ctaaaacata ccagatagtt ggtttacact ttgt | 774 |

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| tctata | cgaa | aactacatat | ataacactac | tgagcaaaaa | gttcgggggt | tegggegeee | 480 |
|---|------------------------|-------------|--------------|--------------|--------------|------------|--------|
| ctcccg | gccc | cttcaaagct | tcgccaatgt | ctctgaaccg | aagaaaaccc | tcactcgtct | 540 |
| actage | caat | gaatcctcac | cagggaaacc | ctcactcgtc | ttactggact | attggcgctt | 600 |
| ccaaat | ggac | tacttgcgaa | attcaccaca | tcgggataca | ctcgtctact | gcggtgaggt | 660 |
| aaaacc | cgct | tggctcaagg | atcgaactag | cgattgctgc | ctactcgcct | aatctcccat | 720 |
| catcaa | cagg | tgccgccgaa | acaaaatgct | gggggcggga | gttgaaccta | ggtccagtga | 780 |
| cgcacco | catg | aattttttt | ctagggatgc | gaacgagtgg | tttaaccata | cttttaagag | 840 |
| gtgcgat | tcgg | aaattttacc | tataaaatac | actaaaaaag | ttccaagggt | ccacccaccc | 900 |
| cttaaco | ctaa | gtccgccttt | gtctggatca | cgtgaaacat | caggtctctc | ccttaccagt | 960 |
| ccagcta | acga | ctcattgaca | aaatatcaaa | accatatgat | tttgagtttt | atctcaaccg | 1020 |
| aaagtga | acat | catgacagag | aatcgacata | accaaaacgt | gtaaacgtac | aactcaccat | 1080 |
| tgcgttg | gaaa | aggacaaaac | aggtaggatt | cttgtcaaat | tcaacgcgta | cacctgtgct | 1140 |
| tcatcta | aaac | cccatacttt | aagaaccttt | ataaagacca | ctcactatat | atacacatat | 1200 |
| ataatat | ccac | ttatcaaacc | С | | | | 1221 |
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| <223> | Desi II s | | nucleotide k | pased on the | e promoter a | and having | Hind I |
| <400> 4 gcgaagcttg atgcgaacga gtggttta | | | | 28 | | | |
| 010 | _ | | | | | | |

- <210> 5
 <211> 28
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- site
- <400> 5
 gcggtccaca cctggcacat cgtatctt 28
- <210> 6 <211> 27

| <212> <213> | DNA Artificial Sequence | |
|---------------------------|--|-----|
| <220> <223> | Designed oligonucleotide based on the promoter and having Bam site | HI |
| <400> cgcgga | 6 teeg agggtttgat aagtgat | 27 |
| <210><211><211><212><213> | 7 27 DNA Artificial Sequence | |
| <220> <223> | Designed oligonucleotide based on the promoter and having Hind II site | d I |
| <400> cccaag | 7 ctta acctaagtee geetttg | 27 |
| <210><211><211><212><213> | 27 | |
| <220> <223> | Designed oligonucleotide based on the promoter and having Hind I site | II |
| <400> ggcaag | 8 ctta tctcaaccga aagtgac | 27 |
| | | |
| <220> <223> | Designed oligonucleotide based on the 5' promoter | |
| <400> atttcg | 9 caag tagtccatt | 19 |
| | 1015 | |
| | attg gaccacctgg cacatcgtat cttatctctt ttqtcqtttc caacacacca | 60 |

| caacacacct | acaaacgtgt | caattcacac | ttcaccaatt | tcatttcctt | ttagtcaatc | 120 |
|------------|------------|------------|------------|------------|------------|------|
| atattaaaag | tagtagcccc | cacccccatt | tgttacctac | catttcccac | tttaataatc | 180 |
| acccacgcta | tgtccacttg | tacttttgtt | tgcacacaac | tcttcccata | aaatatcaaa | 240 |
| ccaaattttt | tttaatggaa | aacaaatact | tcaaatgcac | tattggtgaa | attcaccaca | 300 |
| tcagaataca | cccgtctcta | ctcatctact | ggccaacgaa | tcttcacggg | ggaaaccctc | 360 |
| actcgtctac | tgggactact | ggcgcttcaa | aatggactac | tgacaaaatt | caccacatcg | 420 |
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| cgatcgccac | ccactcacct | tgtctcccat | catcaccagg | tgccgccaaa | acaaaatgtt | 540 |
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| actaaaaaaa | tttcaagggt | ccgcccaccc | accccttaac | ctaagtccgc | ctctgcctgg | 720 |
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| caaaaccata | tgattttgag | ttttatctca | accgaaagtg | acatcatgac | agagaatcga | 840 |
| cataaccaaa | acgtgtaaac | gtacaactca | ccattgcgtt | gaaaaggaca | aaacaggtag | 900 |
| gattcttgtc | aaattcaacg | cgtacacctg | tgcttcatct | aaaccccata | ctttaagaac | 960 |
| ctttataaag | accactcact | atatatacac | atatataata | tcacttatca | aaccc | 1015 |
| <210> 11 | | | | | | |

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- <213> Artificial Sequence
- <220>
- <223> Designed oligonucleotide that matches nucleotides 81-100 of the H ahb-4 cDNA sequence and having Bam HI site
- <400> 11
- ggcggatcca acagaaacaa ccaccagg
- <210> 12
- <211> 29
- <212> DNA
- <213> Artificial Sequence
- <220>
- Designed oligonucleotide for cloning 5' cDNA and having $\,$ Bam HI $\,s$ <223>
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- ggcggatccc ctggtggttg tttctgttg

28

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gaggactcga gctcaagc
                                                                     18
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acctttataa agaccactc
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| <400> acgcaa | <400> 17 acgcaatggt gagttgtac | | | |
|-----------------|---------------------------------------|----|--|--|
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| <211> | 30 | | | |
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| <213> | Artificial Sequence | | | |
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| | | 30 | | |
| | | | | |
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Ser Leu Lys Lys Glu Asn Gln Ala Leu Leu Asn Gln Leu Glu Val Leu

100 105 110

Arg Asn Val Ala Glu Lys His Gln Glu Lys Thr Ser Ser Gly Ser 115 120 125

Gly Glu Glu Ser Asp Asp Arg Phe Thr Asn Ser Pro Asp Val Met Phe 130 135 140

Gly Gln Glu Met Asn Val Pro Phe Cys Asp Gly Phe Ala Tyr Phe Glu 145 150 155 160

Glu Gly Asn Ser Leu Leu Glu Ile Glu Glu Gln Leu Pro Asp Pro Gln
165 170 175

Lys Trp Trp Glu Phe 180

<210> 25

<211> 99

<212> PRT

<213> Artificial Sequence

<220>

<223> Synthetic Hd-Zip domain of Athb-1

<400> 25

Leu Pro Glu Lys Lys Arg Arg Leu Thr Thr Glu Gln Val His Leu Leu 1 5 10 15

Glu Lys Ser Phe Glu Thr Glu Asn Lys Leu Glu Pro Glu Arg Lys Thr 20 25 30

Gln Leu Ala Lys Lys Leu Gly Leu Gln Pro Arg Gln Val Ala Val Trp $35 \hspace{1cm} 40 \hspace{1cm} 45$

Phe Gln Asn Arg Arg Ala Arg Trp Lys Thr Lys Gln Leu Glu Arg Asp 50 55 60

Tyr Asp Leu Leu Lys Ser Thr Tyr Asp Gln Leu Leu Ser Asn Tyr Asp 65 70 75 80

Ser Ile Val Met Asp Asn Asp Lys Leu Arg Ser Glu Val Thr Ser Leu 85 90 95

Thr Glu Lys

<210> 26

<211> 99

<212> PRT

<213> Artificial Sequence

<220>

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<400> 26

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Glu Lys Asn Phe Glu Leu Glu Asn Lys Leu Glu Pro Glu Arg Lys Val
20 25 30

Lys Leu Ala Gl
n Glu Leu Gly Leu Gl
n Pro Arg Gl
n Val Ala Val Trp\$35\$ 40 45

Phe Gln Asn Arg Arg Ala Arg Trp Lys Thr Lys Gln Leu Glu Lys Asp 50 55 60

Tyr Gly Val Leu Lys Thr Gln Tyr Asp Ser Leu Arg His Asn Phe Asp 65 70 75 80

Ser Leu Arg Arg Asp Asn Glu Ser Leu Leu Gln Glu Ile Ser Lys Leu 85 90 95

Lys Thr Lys

<210> 27

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<212> PRT

<213> Artificial Sequence

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Asn Lys Asn Asn Gln Arg Arg Phe Ser Asp Glu Gln Ile Lys Ser Leu 1 5 10 15

Glu Met Met Phe Glu Ser Glu Thr Arg Leu Glu Pro Arg Lys Lys Val

20 25 3

Gln Leu Ala Arg Glu Leu Gly Leu Gln Pro Arg Gln Val Ala Ile Trp 35 40 45

Phe Gln Asn Lys Arg Ala Arg Trp Lys Ser Lys Gln Leu Glu Thr Glu 50 55 60

Tyr Asn Ile Leu Arg Gln Asn Tyr Asp Asn Leu Ala Ser Gln Phe Glu 65 70 75 80

Ser Leu Lys Lys Glu Lys Gln Ala Leu Val Ser Glu Leu Gln Arg Leu 85 90 95

Lys Glu Ala

<210> 28

<211> 99

<212> PRT

<213> Artificial Sequence

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<223> Synthetic Hd-Zip domain of Athb-12

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Lys Ser Asn Asn Gln Lys Arg Phe Asn Glu Glu Gln Ile Lys Ser Leu 1 5 10 15

Glu Leu Ile Phe Glu Ser Glu Thr Arg Leu Glu Pro Arg Lys Lys Val 20 25 30

Gln Val Ala Arg Glu Leu Gly Leu Gln Pro Arg Gln Met Thr Ile Trp 35 40 45

Phe Gln Asn Lys Arg Ala Arg Trp Lys Thr Lys Gln Leu Glu Lys Glu 50 55 60

Tyr Asn Thr Leu Arg Ala Asn Tyr Asn Asn Leu Ala Ser Gln Phe Glu 65 70 75 80

Ile Met Lys Lys Glu Lys Gln Ser Leu Val Ser Glu Leu Gln Arg Leu 85 90 95

Asn Glu Glu

210 > 29
211 > 99
212 > PRT
213 > Artificial Sequence

220 >
223 > Synthetic Hd-Zip domain of Hahb-4

4400 > 29

Arg Asn Glu Gly Arg Lys Arg Phe Thr Asp Lys Gln Ile Ser Phe Leu 1

Glu Tyr Met Phe Glu Thr Gln Ser Arg Pro Glu Leu Arg Met Lys His 20

Gln Leu Ala His Lys Leu Gly Leu His Pro Arg Gln Val Ala Ile Trp 45

Phe Gln Asn Lys Arg Ala Arg Ser Lys Ser Arg Gln Ile Glu Gln Glu 50

Tyr Asn Ala Leu Lys His Asn Tyr Glu Thr Leu Ala Ser Lys Ser Glu 80

Ser Leu Lys Lys Glu Asn Gln Ala Leu Leu Asn Gln Leu Glu Val Leu 90

Arg Asn Val

<210> 30

<211> 66

<212> PRT

<213> Artificial Sequence

<220> 30

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Ala Glu Lys His Gln Glu Lys Thr Ser Ser Ser Gly Ser Gly Glu Glu 1 5 10 15

Ser Asp Asp Arg Phe Thr Asn Ser Pro Asp Val Met Phe Gly Gln Glu 20 25 30

Met Asn Val Pro Phe Cys Asp Gly Phe Ala Tyr Phe Glu Glu Gly Asn 35 40 45

Ser Leu Leu Glu Ile Glu Glu Gln Leu Pro Asp Pro Gln Lys Trp Trp 50 55 60

Glu Phe 65

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CHAN et al.

Appl. No.: 10/520,033

§ 371 date: December 30, 2004

For: Transcription Factor Gene Induced by Water Deficit

Conditions And Abscisic Acid From Helianthus Annuus, Promoter And

Transgenic Plants

Confirmation No.: 2792

Art Unit: 1638

Examiner: Vinod Kumar

Atty. Docket: 2510.0040000/JAG/SAC

Amendment and Reply Under 37 C.F.R. § 1.111

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated February 22, 2008, Applicants submit the following Amendment and Remarks.

Amendments to the Specification begin on page 3 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 6 of this paper.

Amendments to the Drawings begin on page 10 of this paper and include both an attached replacement sheet and an annotated sheet showing changes.

Remarks and Arguments begin on page 11 of this paper.

An Appendix including amended drawing figures is attached following page 32 of this paper.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent

abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Specification

Please insert the Substitute Sequence Listing that is appended hereto at the end of the specification.

Please replace the paragraph starting on page 4, line 1 with the following paragraph:

It is therefore an object of the invention to provide an isolated nucleic acid molecule encoding the transcription factor *Hahb-4*, a functionally active fragment or variant thereof, having the nucleic acid sequence of <u>SEQ ID NO:1 SEQ ID No 1</u> or a fragment thereof, wherein the nucleic acid molecule is derived from *Helianthus annuus*, and it may be an mRNA or the cDNA of <u>SEQ ID NO:2 SEQ ID No 2</u>, wherein the molecule is capable of binding to a 5'-CAAT(A/T)ATTG-3' DNA sequence (<u>SEQ ID NO:23</u>) or to a dehydration transcription regulating region of plant species.

Please replace the paragraph starting on page 9, line 6 with the following paragraph:

It is a further object of the present invention to provide a transgenic plant stably transformed with at least one of the above mentioned constructs, wherein the protein of interest is the transcription factor *Hahb-4*, having the nucleic acid sequence selected from the group comprising SEQ ID NO:1, SEQ ID NO:2 SEQ ID N° 1, SEQ ID N° 2 and fragments thereof, and wherein the plant is selected from the group comprising monocot and dicot plants and said plant is environmental stress tolerant to situations like drought, high salinity, high osmotic pressure and others, and preferably the plant is

resistant and tolerant to water deficit. Most preferably, the plant is water stress tolerant by binding the transcription factor *Hahb-4* or a functionally active fragment or variant thereof to a dehydration transcription regulating region of the plant and the dehydration transcription regulating region of the plant is a 5'-CAAT(A/T)ATTG-3' DNA sequence (SEQ ID NO:23).

Please replace the paragraph starting on page 10, line 4 with the following paragraph:

Figure 1 shows the genomic sequence encoding sunflower *Hahb-4* of the invention. The deduced protein sequence of the open reading frame (SEQ ID NO:24) is indicated below the nucleotide sequence (SEQ ID NO:1). The homeodomain is shown in bold; leucines from the leucine zipper are shown in bold and underlined. The lower part of the Figure shows an alignment of the Hd-Zip domain of *Hahb-4* (SEQ ID NO:29) with those of *Athb-1* (SEQ ID NO: 25), -6 (SEQ ID NO: 26), -7 (SEQ ID NO:27) and -12 (SEQ ID NO:28). Shaded boxes indicate identical amino acids.

Please replace the paragraph starting on page 14, line 12 with the following paragraph:

Figure 18 shows the sequence of nucleotides of the promoter region of *Hahb-*4 gene (SEQ ID NO:3), remarking the sequences corresponding to the TATA box, the element responding to water stress/low temperatures, ABRE regions and the sequences indicating the recognizing sites of Myb and Myc.

Please replace the paragraph starting at page 15, line 14 with the following paragraph:

Figure 23 shows a scheme of *Hahb-4* gene structure. At the top: large <u>allele</u> allelee, at the bottom: small <u>allele</u> allelee. The oligonucleotides employed for the isolation of the promoting region and for the construction of recombinant plasmids and used in plant transformation are indicated.

Please replace the paragraph beginning on page 47, line 20 of the specification with the following paragraph:

The PCR reactions in the first step were made by using as a template the DNA from the recycling of the fragments digested with SauIIIA, with oligonucleotides IPCR0/IPCR1 (SEQ ID NO:12/SEQ ID NO:15) (SEQ ID N° 12/SEQ ID N° 15) and in the case of the DNA digested with HindIII, the employed oligonucleotides were IPCR2/IPCR3 (SEQ ID NO:16/SEQ ID NO:17) (SEQ ID N° 16/SEQ ID N° 17). The obtained fragments were cloned in pGEM®-T easy vector (Promega), according to the protocol suggested by the manufacturer. Once the cloning was verified, the corresponding sequence was determined and the oligonucleotides necessary for the next step were designed. The sequence and location of the oligonucleotides used in the next cloning steps are shown in Figure 23:

IPCR0 [5'-GGCGGATCCCCTGGTGGTTGTTTCTGTTG-3'] (SEQ ID NO:12)

IPCR1 [5'-GCCGAATTCAGATTGAGCAAGAGTATAAC-3'] (SEO ID NO:15)

IPCR2 [5'-ACCTTTATAAAGACCACTC-3'] (SEQ ID NO:16)

IPCR3 [5'-ACGCAATGGTGAGTTGTAC-3'] (SEQ ID NO:17)

IPCR4 [5'-GCGAAGCTTGATGCGAACGAGTGGTTTA] (SEQ ID NO:4)

IPCR5 [5'-ATTTCGCAAGTAGTCCATT-3'] (SEQ ID NO:9)

IPCR6 [5'-CCCAAGCTTAACCTAAGTCCGCCTTTG-3'] (SEQ ID NO:7)

IPCR7 [5'-GGCAAGCTTATCTCAACCGAAAGTGAC-3] (SEQ ID NO:8)

Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

Claims 1-9. Cancelled.

Claim 10 (Currently amended). A transgenic plant stably transformed with a nucleic acid molecule comprising having a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 selected from the group comprising SEQ ID N° 1, SEQ ID N° 2 and fragments thereof, wherein the nucleic acid molecule encodes the transcription factor *Hahb 4* or a functionally active fragment or variant thereof, wherein the nucleic acid molecule is expressed in the plant and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant under the same conditions.

Claims 11-13. Cancelled.

Claim 14 (Original). The transgenic plant of claim 10, wherein the plant is a monocot.

Claim 15 (Original). The transgenic plant of claim 10, wherein the plant is a dicot.

Claim 16. Cancelled.

Claim 17 (Currently amended). A plant seed stably transformed with a nucleic acid molecule comprising having a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 a sequence selected from the group comprising SEQ ID N° 1, SEQ ID N° 2 and fragments thereof, wherein the nucleic acid molecule encodes the transcription factor *Hahb 4* or a functionally active fragment or variant thereof, wherein the nucleic acid molecule is expressed in the seed and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant seed under the same conditions.

Claim 18 (Currently amended). A plant host cell that has been stably transformed with a nucleic acid molecule comprising having a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 having a sequence selected from the group comprising SEQ ID N° 1, SEQ ID N° 2 and fragments thereof, wherein the nucleic acid molecule encodes the transcription factor *Hahb 4* or a functionally active fragment or variant thereof, wherein the nucleic acid molecule is expressed in the plant host cell.

Claims 19-20, Cancelled.

Claim 21 (Currently amended). A method of producing a water stress tolerant transgenic plant, the method comprising:

stably transforming a plant cell or cell culture with a nucleic acid molecule comprising having a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 the nucleic acid sequence selected from the group comprising SEQ ID N° 1, SEQ ID N° 2 and fragments thereof, wherein the nucleic acid is expressed in the plant cell or cell culture; and

regenerating the <u>cell or cell culture</u> cells or cell cultures into <u>a plant</u> plants.

Claims 22-40. Cancelled.

Claim 41 (New). The transgenic plant of claim 10, wherein said nucleic acid sequence encodes SEQ ID NO:24.

Claim 42 (New). The transgenic plant of claim 10, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2.

Claim 43 (New). The plant seed of claim 17, wherein said nucleic acid sequence encodes SEQ ID NO:24.

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Claim 44 (New). The plant seed of claim 17, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2.

Claim 45 (New). The plant host cell of claim 18, wherein said nucleic acid sequence encodes SEQ ID NO:24.

Claim 46 (New). The plant host cell of claim 18, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2.

Claim 47 (New). The method of claim 21, wherein said nucleic acid sequence encodes SEQ ID NO:24.

Claim 48 (New). The method of claim 21, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2.

Amendments to the Drawings

The attached replacement sheets of drawings, which include Figures 1, 2, and 23, replace the original drawings. The replacement drawings are being submitted to remove the frames in order to comply with 37 C.F.R. § 1.84(g).

Attachment: Replacement Sheets

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 10, 14, 15, 17, 18, 21 and 41-48 are pending in the application, with claims 10, 17, 18 and 21 being the independent claims. Claims 1-9, 11-13, 16, 19, 20 and 22-40 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 41-48 are sought to be added. Support for the new claims may be found in original claims 10, 17, 18, and 21 and in the specification at page on page 10, lines 5-6. Claims 10, 17, 18 and 21 are sought to be amended. Support for the amendment to the claims may be found in the claims as originally filed and in the specification at page 21, line 4 through page 25, line 24, Examples 1-4 and Figure 1. Support for SEQ ID NO:30 may be found in Figure 1 which shows that the Hd-Zip domain of Hahb-4 ends at amino acid 115 of SEQ ID NO:24. Thus, SEQ ID NO:30 encompasses amino acids 116 through 181 of SEQ ID NO:24. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Summary of the Office Action

In the Office Action dated February 22, 2008, the Examiner has made two objections to the specification, one objection to the drawings, sixteen objections of the

claims and five rejections of the claims. Applicant respectfully offers the following remarks concerning each of these elements of the Office Action.

III. The Objections to the Specification Should Be Withdrawn

In section 2 of the Office Action at pages 2-3, the specification was objected to for failing to identify certain nucleotide sequences by sequence identifiers as required by 37 C.F.R. § 1.821. Applicants have amended the specification to insert the required sequence identifiers. Thus, this objection has been accommodated and should be reconsidered and withdrawn.

In addition, filed herewith is a Substitute Sequence Listing in paper form and in computer readable form. The Substitute Sequence Listing is being filed to add sequences from the as-filed specification and drawings. Support for these sequences may be found in the specification and drawings at page 4, lines 6-7 and Figure 1. In accordance with 37 C.F.R. §§ 1.821-1.825, the paper and computer readable forms of the Substitute Sequence Listing submitted herewith are identical and contain no new matter. The specification has been amended to direct the entry of the Substitute Sequence Listing. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Finally, in section 3 of the Office Action at page 3, the Examiner has objected to the specification for the misspelling of "alleloe." Applicants have corrected the spelling of "alleloe" to "allele." Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

IV. The Objections to the Drawings Should Be Reconsidered and Withdrawn

In section 4 of the Office Action at pages 3-4, Figures 1, 2 and 20-23 were objected to for allegedly failing to comply with 37 C.F.R. § 1.84(g) because the figures are framed. With regard to Figures 1, 2 and 23, Applicants submit three sheets of formal replacement drawings in order to comply with 37 C.F.R. § 1.84(g). Identification of the replacement drawing sheets submitted herewith are provided in accordance with 37 C.F.R. §§ 1.84(c) and 1.121(d). Acknowledgement of the receipt, approval, and entry of the replacement drawing sheets into this application are respectfully requested.

However, with regard to Figures 20-22, Applicants respectfully request reconsideration of this objection. Figures 20-22 are photographs and not text. If the lines around these figures were removed, it would not be apparent where the photograph ends. Thus, Applicants respectfully request that the Examiner reconsider and withdrawal the objection of Figures 20-22.

V. The Objections to the Claims Should Be Withdrawn

In section 5 of the Office Action at pages 4-6, claims 1-4, 6-12 and 16-21 have been objected to due to informalities. However, as indicated above, Applicants have cancelled claims 1-4, 6-9, 11-12, 16, 19 and 20, thus rendering most the objection as applied to these claims.

Claims 10, 17, 18 and 21 were objected to for reciting "comprising." Claims 10, 17, 18 and 21 have been amended to remove the language. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

Claim 21 was objected to for grammatical errors. Claim 21 has been amended to correct these grammatical errors. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

VI. The Rejection under 35 U.S.C. § 112, Second Paragraph is Moot

In section 6 of the Office Action at pages 6-7, claim 8 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for providing insufficient antecedent basis. Applicants respectfully disagree. However, as indicated above, claim 8 has been cancelled without prejudice or disclaimer thereof. Thus, this rejection is rendered moot. Reconsideration and withdrawal of the rejection are respectfully requested.

VII. The Rejections Under 35 U.S.C. § 112, First Paragraph are Traversed

A. Enablement

In section 7 of the Office Action at pages 7-15, claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly would not be enabling for "(a) a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor *Hahb-4*, and (b) a nucleic acid sequence having a fragment of SEQ ID NO:1 or SEQ ID No:2." *See* Office Action at page 7. Applicants respectfully disagree. However, as indicated above, Applicants have cancelled claims 1-9, 11-13, 16, 19, and 20, thus rendering moot the rejection as applied to these claims. In addition, in an effort to facilitate prosecution, and not in acquiescence to the Examiner's rejection Applicants have amended claims 10, 17, 18 and 21 to remove the "functionally active"

fragment or variant thereof' and "fragments thereof' language. However, inasmuch as the amended claims incorporate similar language from the previously pending claims to which the Examiner rejected, Applicants respectfully traverse the rejection with the following arguments.

First, Applicants agree with the Examiner that in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the claimed invention must be enabled so that a person of skill in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). However, some experimentation, *e.g.*, testing and screening, even a considerable amount in order to make the invention, is not "undue" if, *e.g.*, it is merely routine. *Id.* Applicants assert that it would require no more than routine experimentation for a skilled artisan to practice the full scope of the claimed invention in view of the teachings in the specification and the knowledge available in the art. Thus, the enablement requirement of 35 U.S.C. § 112, first paragraph, is fully satisfied for the currently pending claims.

As indicated above, amended claims 10 and 17 are directed to a transgenic plant or plant seed stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant or seed and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant or seed under the same conditions. Amended claim 18 is directed to a plant host cell transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3'

DNA sequence attached to SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant host cell. Amended claim 21 is directed to a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30 in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

The Examiner asserts that "the instant specification fails to provide guidance on how to make a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4 having the functional activity (e.g. drought tolerance) of Hahb-4 protein." Office Action at page 9. The Examiner further asserts that "it would be highly unpredictable that a fragment of Hahb-4 protein having DNA (5'-CAAT(A/T)ATTG-3') binding activity alone would be sufficient for producing an environmental stress tolerance when overexpressed in a plant." Office Action at page 13. While Applicants agree with the Examiner that altering the sequence downstream of the Hd-Zip domain of Hahb-4 may be unpredictable, Applicants respectfully assert that making and using a transgenic plant, plant seed, plant host cell stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30, would not require undue experimentation.

As noted above, SEQ ID NO:30 defines the exact polypeptide sequence of HAHB-4 (SEQ ID NO:24) immediately following the Hd-Zip domain through the end of the protein, *i.e.*, amino acids 116-181 of SEQ ID NO:24. Thus, Applicants respectfully

point out that the claims, as currently presented, require that the expressed protein contains not only a functionally defined Hd-Zip binding domain, but also the sequence-defined downstream region of the Hahb-4 protein (SEQ ID NO:30). Therefore, Applicants respectfully assert that the transgenic plants or plant seeds expressing such a protein would exhibit an increased tolerance to drought. Thus, to practice the full scope of the claimed invention, the skilled artisan would only need to be able to: (a) obtain nucleic acid molecules that encode polypeptides comprising a Hd-Zip domain attached to SEQ ID NO:30, (b) test them for the ability to bind to a 5'-CAAT(A/T)ATTG-3' DNA sequence, (c) stably transform a transgenic plant, plant seed, or plant host cell with a nucleic acid molecule that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence, and (d) express the nucleic acid molecule in the transgenic plant, plant seed or plant host cell. All of these processes would be routine in the art and are readily taught in the specification.

Applicants respectfully point out that in order to practice the claimed invention, a skilled artisan would not need to be able to predict the structural and/or functional consequences of particular mutations or base changes, *i.e.*, which particular amino acids to change within the Hd-Zip domain. However, even though Applicants are not required to point out which mutations to make, the specification clearly describes examples of Hd-Zip domains and includes an alignment showing the conserved residues within the Hd-Zip domain. *See*, *e.g.*, the specification at page 10, lines 4-11 and Figure 1. Thus, the specification clearly lays out the amino acid residues that would be amenable to alteration based on the structure of the Hd-Zip domain.

Furthermore, the structure of Hd-Zip domains was well known in the art when the present application was filed. See Sessa et al., J. Mol. Biol. 274:303-309 (1997) (copy attached as Exhibit 1). Sessa et al. provides a detailed analysis of the structure of the Hd-Zip domain present in numerous polypeptides, and the residues necessary for the DNA-binding function. Thus, one of skill in the art would know what substitutions, deletions, and insertions could be made to the nucleic acid sequence, but still retain the function of the Hd-Zip domain. Therefore, in addition to the guidance provided in the specification for the conserved residues of the Hd-Zip domain, knowledge in the art also provides information pertaining to the conserved residues of Hd-Zip domains.

Once obtained, nucleic acid molecules that encode polypeptides comprising a Hd-Zip domain attached to SEQ ID NO:30 can easily be tested for the ability to bind a 5'-CAAT(A/T)ATTG-3' DNA sequence using routine techniques. For example, the present specification teaches assays, such as an electrophoretic mobility shift assay (EMSA) that could be routinely used by one of ordinary skill in the art to test whether variants had the required function. *See* specification at page 19, line 16 through page 20, line 8 and page 39, line 10 through page 40, line 2. Thus, the full range of nucleic acid molecules encompassed by the pending claims can be made and analyzed by persons of ordinary skill in the art using only routine methods and experimentation.

Admittedly, the above processes may result in the production of nucleic acid molecules that encode proteins comprising a Hd-Zip domain attached to SEQ ID NO:30, but *do not* bind a 5'-CAAT(A/T)ATTG-3' DNA sequence. The skilled artisan, however, would be able to easily identify and discard such non-active molecules that do not fall within the scope of the claimed invention. Screening for molecules that possess a

particular activity is common in the biological arts. Experimentation, even complex experimentation, is not undue if the art typically engages in such experimentation. See In re Certain Limited-Charge Cell Culture Microcarriers, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985); see also Wands, 858 F.2d at 737, 8 USPQ2d at 1404. For example, in concluding that practicing the claimed invention would not require undue experimentation, the court in Wands stated that, "[t]he nature of monoclonal antibody technology is that it involves screening hybridomas [often hundreds at a time] to determine which ones secrete antibody with desired characteristics[, and p]ractitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." Wands, 858 F.2d at 738, 740, 8 USPQ2d at 1405, 1406.

Thus, the uncertainty that may be associated with predicting protein function from sequence data is of little relevance in an analysis of the enablement of Applicants' claims. Much like the practitioners in *Wands* screening hundreds of hybridomas for monoclonal antibodies with the desired characteristics, a skilled artisan would be expected to engage in screening for nucleic acid molecules that encode proteins comprising a Hd-Zip domain attached to SEQ ID NO:30 and bind a 5'-CAAT(A/T)ATTG-3' DNA sequence. Such screening, even if it resulted in the identification of a molecule not having the desired activity, would be considered routine in the art and would be acknowledged as an integral part of making the nucleic acid molecules.

In view of the forgoing discussion, Applicants submit that a person having ordinary skill in the art, in view of the teachings of the specification, would be able to make and practice the full scope of Applicants' claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Written Description

In section 8 of the Office Action at pages 15-19, claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the written description requirement. As indicated above, Applicants have cancelled claims 1-9, 11-13, 16, 19, and 20, thus rendering moot the rejection as applied to these claims. In addition, in an effort to facilitate prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amend claims 10, 17, 18 and 21 to remove the "functionally active fragment or variant thereof" and "fragments thereof" language. However, inasmuch as the amended claims incorporate similar language from the previously pending claims to which the Examiner rejected, Applicants respectfully traverse the rejection with the following arguments.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case,

Applicants assert that the Examiner has not met this burden with regard to the currently pending claims.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. In addition, the written description requirement must be viewed in light of the state of the art at the time of filing. *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed Cir. 2005). Applicants submit that, when viewed in light of the state of the art at the time of filing the present application, the specification fully supports the presently claimed invention.

The Examiner asserts that "[t]he specification does not describe the structure of Hahb-4 variant(s), and thus their function is unknown." Office Action at page 18. The Examiner further asserts that "[t]here is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional (environmental stress tolerance) activity of the Hahb-4 protein." Office Action at page 18. With regard to the currently pending claims, Applicants respectfully disagree.

Applicants respectfully contend that the specification as filed provides an adequate written description for transgenic plants, plant seeds, and plant host cells stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30.

. As discussed above, SEQ ID NO:30 defines the exact polypeptide sequence of HAHB-4 (SEQ ID NO:24) immediately following the Hd-Zip domain through the end of

the protein, *i.e.*, amino acids 116-181 of SEQ ID NO:24. Thus, Applicants respectfully point out that the claims, as currently presented, require that the expressed protein contains not only a functionally defined Hd-Zip binding domain, but also the sequence-defined downstream region of the Hahb-4 protein (SEQ ID NO:30). Therefore, Applicants respectfully assert that the transgenic plants or plant seeds expressing such a protein would exhibit an increased tolerance to drought due to the requirement for the specified sequence of SEQ ID NO:30.

With regard to the functionally defined Hd-Zip domain, the specification provides considerable guidance about Hd-Zip domains and includes an alignment showing the conserved residues within the Hd-Zip domain. *See, e.g.*, the specification at page 10, lines 4-11 and Figure 1. Thus, the specification clearly lays out the amino acid residues that would be amenable to alteration based on the structure of the Hd-Zip domain, without affecting the ability of the protein to bind to the 5'-CAAT(A/T)ATTG-3' DNA sequence.

In addition, as indicated above, the structure of Hd-Zip domains was well known in the art when the present application was filed. *See* Sessa *et al.*, J. Mol. Biol. 274:303-309 (1997) (copy attached as Exhibit 1). Sessa *et al.* provides a detailed analysis of the structure of the Hd-Zip domain present in numerous polypeptides, and the residues necessary for the DNA-binding function. Given that the skilled artisan would have been familiar with this common structural core among Hd-Zip domains and given the teachings of the present application, the skilled artisan could clearly envision the sequences that would retain the functional requirement of binding to the 5'-CAAT(A/T)ATTG-3' DNA sequence. As noted in *Capon*, when the prior art includes

the relevant information, "precedent does not set a *per se* rule that the information must be determined afresh." *Capon*, 418 F.3d at 1358. Thus, it would be readily apparent to the skilled artisan that the Applicants had "invented what is claimed" *Vas-Cath*, 935 F.2d at 1563. Accordingly, one skilled in the art, enlightened by the teachings of the present application and the knowledge in the art, could readily envision all of the various polypeptide sequences of the specified polypeptides.

Applicant asserts that the specification conveys with reasonable clarity that the Applicant was in possession of the claimed invention and that the claims are fully supported by the specification. For all of the above reasons, Applicant respectfully asserts that the present specification provides sufficient written description to convey to one of ordinary skill that Applicant had possession of the full scope of the claimed invention upon filing of the application. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

VIII. The Rejection Under 35 U.S.C. § 102 is Rendered Moot

In section 9 of the Office Action at pages 19-21, claims 1-8 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gago *et al.* (*Plant, Cell and Environment 25*:633-640 (2002)) (hereinafter "Gago"). However, as indicated above, claims 1-8 have been cancelled without prejudice or disclaimer thereof. Thus, this rejection is rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

IX. The Rejection Under 35 U.S.C. § 103 is Traversed

In section 11 of the Office Action at pages 22-25, claims 9-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Gago in view of Bidney *et al.* (U.S. Patent No. 6,265,638) (hereinafter "Bidney"). As indicated above, solely in an effort to advance prosecution, and not in acquiescence to any reasoning underlying the Examiner's rejection, Applicants have canceled claims 9, 11-13, 16, 19, and 20 without prejudice or disclaimer of the subject matter therein. Hence, the objection to these claims has been rendered moot. Applicants respectfully traverse this rejection with respect to the remaining claims.

The Examiner asserts that:

it would have been prima facie obvious to one of ordinary skill in the art to transform any plant species with a nucleic acid sequence encoding Gago et al. Hahb-4 protein using any method of plant transformation including the one taught by Bidney et al. to obtain a transgenic plant...overexpressing Hahb-4 protein.

Office Action at pages 24-25. The Examiner further asserts that because:

Gago et al. clearly teach that Hahb-4 protein is induced...in a plant...in response to drought or water stress, and Hahb-4 protein regulates the expression of drought inducible promoter(s) through its binding with the dehydration responsive elements present within said promoter, one of ordinary skill in the art would have been motivated to overexpress a nucleic acid sequence encoding...Hahb-4 protein in any plant...for the purpose of obtaining a water stress (drought) tolerant transgenic plant with reasonable expectation of success.

Office Action at page 25. Applicants respectfully disagree with these statements.

The United States Supreme Court addressed the issue of obviousness in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007). The Court stated that the

Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966) factors still control an obviousness inquiry. Those factors are: 1) "the scope and content of the prior art"; 2) the "differences between the prior art and the claims"; 3) "the level of ordinary skill in the pertinent art"; and 4) objective evidence of nonobviousness (KSR, 127 S.Ct. at 1734 (quoting Graham, 383 U.S. at 17-18).

The USPTO has recently published guidelines for Examiners in determining whether claims are non-obvious under the KSR holding. 72 FR 57526. In particular, the Office requires that Examiners articulate, in the record, specific findings of fact which, in view of the legal considerations under *Graham*, would render the claimed invention obvious. While the Office sets forth a number of rationales by which a determination of obvious may be made (*Id.* at 57529), a common thread throughout requires that the prior art, in combination with the knowledge ascribed to the person of ordinary skill in the art, provide sufficient information to make the claimed invention fully and easily predictable.

Here, as detailed below, the Examiner has not established a *prima facie* case of obviousness because the Examiner has not adequately shown that the claimed invention was fully and easily predictable.

Furthermore, post-KSR decisions by the Federal Circuit clearly indicate that the requirement for showing a reasonable expectation of success still plays an important role in an obviousness determination and, further, that evidence demonstrating a lack of a reasonable expectation of success must be considered. See, e.g., Takeda Chemical Industries, Ltd. v. Alphapharm PTY., LTD, 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007) (holding that even though a compound similar to the claimed anti-diabetic compound, was known in the prior art, one of ordinary skill would not have had a

reasonable expectation of success in obtaining the claimed invention); and *Forest Laboratories, Inc. v. IVAX Pharmaceuticals, Inc.*, No. 2007-1059, slip op. (Fed. Cir. Sept. 5, 2007) (holding that one of ordinary skill would not have had a reasonable expectation of success in attempting to separate a substantially pure enantiomer even though the racemic mixture was known in the art). In addition, objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts must be considered in every case in which they are present. *See* MPEP §2141.

Here, even assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness, Applicants assert, as detailed below, that the *prima facie* case of obviousness is rebutted by the presentation of failure of others, unexpected and advantageous properties, and long-felt need of the claimed products and method.

A. The Examiner Failed to Establish a Prima Facie Case of Obviousness

As indicated above, amended claims 10 and 17 and thus the remaining claims that depend therefrom are directed to a transgenic plant or plant seed stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant or seed and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant or seed under the same conditions. Amended claim 18 is directed to a plant host cell transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2)

SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant host cell. Amended claim 21 is directed to a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Gago does not disclose, suggest, or otherwise contemplate a transgenic plant, plant seed, or plant host cell that has been stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30. In addition, Gago does not disclose, suggest, or otherwise contemplate that the expression of a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in a transformed plant or plant seed will result in an increased tolerance to drought compared to a wild type plant or plant seed under the same conditions. Furthermore, Gago does not disclose, suggest, or otherwise contemplate a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, expressing the nucleic acid in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Gago only discloses that Hahb-4 is upregulated in response to water stress. However, there is absolutely nothing in Gago to suggest that expression of Hahb-4 would also confer tolerance to drought in sunflowers, let alone other plant species. Despite the Examiner's assertion to the contrary, at the time the application was filed, one of ordinary skill in the art would not have predicted that a transcription factor that is upregulated in response to water stress such as Hahb-4 would thus also confer tolerance to drought. In support of this contention, Applicant provides herewith a Declaration under 37 C.F.R. § 1.132 of Federico Trucco, Ph.D. ("Trucco Declaration"). Indeed, as pointed out in the Trucco Declaration, transcription factors, including those induced by water stress, regulate a wide variety of target genes, many of which may not be involved in drought tolerance. Trucco Declaration at page 2. In addition, even if these transcriptional factors did regulate genes involved in drought tolerance, posttranscriptional modification to the transcription factor could be required in order to induce expression of the downstream target gene. Trucco Declaration at pages 2-3. Thus, in both instances, expression of the transcription factor would not result in a drought tolerant phenotype. Accordingly, based on the state of the art as at the time the application was filed, Applicants respectfully assert that it would not have been predictable that expression of a transcription factor, such as Hahb-4, induced in response to water stress would function to provide an increased tolerance to drought in a transgenic plant because there was not a finite number of predictable outcomes. Thus, in view of the unpredictability in correlating water stress induction with drought tolerance set forth in the Trucco Declaration, Gago fails to provide a reasonable expectation of success that the expression of the Hahb-4 gene in a transgenic plant would result in a

transgenic plant that exhibited increase tolerance to drought as required by the claims. Thus, Gago is deficient as a primary reference upon which to base a *prima facie* case of obviousness.

These deficiencies are not cured by the disclosure of Bidney. Bidney discloses a method of transforming plants using Agrobacterium. Bidney does not disclose, suggest, or otherwise contemplate a transgenic plant, plant seed, or plant host cell that has been stably transformed with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30. In addition, Bidney does not disclose, suggest, or otherwise contemplate that the expression of a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in a transformed plant or plant seed will result in an increased tolerance to drought compared to wild type plant or plant seed under the same conditions. Furthermore, Bidney does not disclose, suggest, or otherwise contemplate a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, expressing the nucleic acid in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Thus, Applicants submit that, upon careful analysis of the cited references and given the unpredictability in the field, the skilled artisan would have found no motivation to combine or modify the reference teachings with a reasonable expectation of success to

arrive at the claimed invention. Accordingly, a *prima facie* case of obviousness has not been established. Applicants respectfully request that the rejection be withdrawn.

B. The Claimed Invention Exhibits Unexpected Results and Long-Felt Need, and There was Failure by Others for the Claimed Invention.

Even assuming, *arguendo*, that the Examiner has established a *prima facie* case of obviousness, Applicants submit that secondary indicia such as unexpected results, long-felt need, and failure by others clearly rebut any such case.

As reaffirmed by the U.S. Supreme Court, courts are "to look at any secondary considerations that would prove instructive," when considering the obviousness of an invention. KSR Int'l. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1739 (April 30, 2007). For example, as set forth in M.P.E.P. § 2141(III), objective evidence or secondary considerations such as unexpected results and the failure of others is relevant to the issue of obviousness and must be considered in every case in which they are present. "Evidence that a compound is unexpectedly superior in <u>one</u> of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." In re Chupp, 816 F.2d 643, 646 (Fed. Cir. 1987) (emphasis added).

The Trucco Declaration explains in detail that there was, and still is, a huge need to develop productive agronomically valued crops that are drought tolerant. Trucco Declaration at page 4. The Trucco Declaration further explains that despite previous failure by others to produce transgenic plants that are drought or water stress tolerant, the present invention provides multiple species of transgenic plants that are unexpectedly drought tolerant. Trucco Declaration at pages 4-6. First, the Trucco Declaration describes two *Arabidopsis* transcription factors that share homology with

Hahb-4 and are induced under water stress but fail to confer drought tolerance to transgenic plants. Trucco Declaration at page 4.

In clear contrast, as explained in the Trucco Declaration, the transgenic plants described in the present invention are unexpectedly drought tolerant. Trucco Declaration at page 5. In addition to the unexpected result that the expression of *Hahb-4* in a dicot (*Arabidopsis*) would result in the development of a drought resistant phenotype, Applicants also demonstrated, using greenhouse studies, that *Hahb-4* can be expressed in and produce a drought resistant phenotype in two different monocots. Trucco Declaration at page 6. Thus, the expression of *Hahb-4* in various species of plants has unexpectedly met a long-felt need of providing productive agronomically valued transgenic plants, which is strong evidence that the claimed composition is not obvious. In view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

X. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Amdt. dated August 22, 2008 - 32 - Reply to Office Action of February 22, 2008

CHAN et al. Appl. No. 10/520,033

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Shannon A. Carroll, Ph.D. Attorney for Applicants Registration No. 58,240

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August 22, 2008

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WRITER'S DIRECT NUMBER:

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Art Unit 1638

Attn: Mail Stop Amendment

Re:

U.S. Utility Patent Application

Application No. 10/520,033; § 371 Date: December 30, 2004

Transcription Factor Gene Induced by Water Deficit Conditions And Abscisic Acid From Helianthus Annuus, Promoter and Transgenic

Plants

Inventors: CHAN et al.

Our Ref: 2510.0040000/JAG/SAC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Credit Card Payment Form (PTO-2038) in the amount of \$525.00 to cover: \$525.00 - Three (3) month extension of time under 37 C.F.R. § 1.17(a)(3);
- 2. Petition for Extension of Time Under 37 C.F.R. § 1.136(a)(1);
- 3. Amendment and Reply Under 37 C.F.R. § 1.111, with Exhibit 1 Exhibit 1: Sessa et al., J. Mol. Biol. 274:303-309 (1997);
- 4. Replacement Drawings Figures 1, 2, 22 and 23 (3 sheets);
- 5. Annotated Drawings Figures 1, 2, 22 and 23 (3 sheets);
- 6. Executed Declaration Under 37 C.F.R. § 1.132 of Federico Trucco, Ph.D., with Exhibits A-L:

Exhibit A: Curriculum Vitae of Federico Trucco, Ph.D.

Exhibit B: Ingram and Bartels, Annu. Rev. Plant Physiol. Plant. Mol. Biol. 47:377-

403 (1996);

Sterne, Kessler, Goldstein & Fox PLLC. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skgf.com

Commissioner for Patents August 22, 2008 Page 2

Exhibit C: Shinozaki and Yamaguchi-Shinozaki, *Plant Physiol.* 115:327-334

(1997)

Exhibit D: Liu et al., The Plant Cell 10:1391-1406 (1998);

Exhibit E: Nakashima and Yamaguchi-Shinozaki, JARQ 39:221-229; (2005);

Exhibit F: Pimentel et al., BioScience 47:97-106 (1997);

Exhibit G: Soderman et al., Plant J. 10:375-381 (1996);

Exhibit H: Lee and Chun, *Plant Mol. Biol.* 37:377-384 (1998);

Exhibit I: Olsson et al., Plant Mol. Biol. 55:663-677 (2004);

Exhibit J: Hjellström et al., Plant Cell and Environment 26:1127-1136 (2003);

Exhibit K: Figure 1 - Evaluation of wheat (Triticum aestivum) GMO lines B and G;

and;

Exhibit L: Figure 2 - Evaluation of maize (Zea mays) GMO lines 3, 6, and 7;

7. 13 pages of paper copy of substitute sequence listing;

8. A computer readable copy of the substitute sequence listing; and

9. Return postcard.

In accordance with 37 C.F.R. § 1.821(f); the paper copy of the sequence listing and the computer readable copy of the sequence listing submitted herewith in the above application are the same.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Shannan a. Cauxll

Shannon A. Carroll, Ph.D. Attorney for Applicants

Registration No. 58,240

JAG/SAC/rjv Enclosures

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Due Date: August 22, 2008

Art Unit: 1638

Confirmation No.: 2792

Application No.: 10/520,033

Examiner: Vinod Kumar

§ 371 Date: December 30, 2004

Applicant: CHAN et al.

Docket: 2510.0040000/JAG/SAC

For: Transcription Factor Gene Induced by Water Deficit

Atty: SAC

Conditions And Abscisic Acid From Helianthus Annuus, Promoter and Transgenic Plants

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKGF Cover Letter;

- 2. Credit Card Payment Form (PTO-2038) in the amount of \$525.00 to cover: \$525.00 Extension of Time fees for three (3) months (small entity);
- Petition for Extension of Time under 37 C.F.R. § 1.136;
- 4. Amendment and Reply Under 37 C.F.R. § 1.111, with Exhibit 1;
- 5. Replacement Drawings Figures 1, 2, 22 and 23 (3 sheets);
- 6. Annotated Drawings in Figures 1, 2, 23 and 23 (3 sheets);
- 7. Executed Declaration Under 37 C.F.R. § 1.132 of Federico Trucco, Ph.D., with Exhibits A-L;
- 8. 13 pages of paper copy of substitute sequence listing;
- 9. A computer readable copy of the substitute sequence listing; and
- 10. Return postcard.



Mail Stop: Amendment

Please Date Stamp and Return to Our Courier

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